



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

14F1-35 - RECALLED  
91093d

19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

WARNING LETTER

April 2, 2001

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

James S. Rosenberg  
President  
Juice Harvest, Inc.  
1055 E. Cooley Avenue  
San Bernardino, CA 92418

W/L 34-01

Dear Mr. Rosenberg:

This letter is in reference to your firm's marketing of "Apple Kiwi Papaya", "Orange Carrot Papaya", "Bee Energized" and "super Green" under the Juice Evolution label:

The labeling for "Apple Kiwi Papaya and Orange Carrot Papaya" make such claims as: "\*\*\*\*Our **Antioxidant** contains **Beta Carotene, Vitamins C & E and Selenium**,\*\*\*providing you with a personal shield against the attack of the free radical.\*\*\*They can damage our cells, impair our immune system, and lead to infections and degenerative diseases. In the process of destroying excessive free radicals **antioxidants** destroy themselves, therefore they must be continually replenished.\*\*\*Maintain your personal shield against the free radical. **Drink your Antioxidants daily.**\*\*\*\*".

The labeling for "Bee Energized" make such claims as "\*\*\*\*\***Bee Energized** is an optimum blend of the ancient healing herbs **Ginseng, Gotu Kola and Ginko Biloba**, with **Bee Pollen** plus the **B Vitamins**. \*\*\***Bee Pollen** is loaded with Amino Acids, enzymes, vitamins and minerals and can help fight fatigue and depression.\*\*\*\*".

Therefore, "Apple Kiwi Papaya", "Orange Carrot Papaya" and "Bee Energized" are misbranded within the meaning of section 403(r)(1)(B) of the Federal Food, Drug and Cosmetic Act (the Act) because the labels bear unauthorized health claims. The claims about fighting depression on the "Bee Energized" product, and antioxidants, free radicals and an impaired immune system on the "Apple Kiwi Papaya" and "Orange Carrot Papaya" are not authorized by regulation or the Act.

The products "Apple Kiwi Papaya", "Orange Carrot Papaya", "Bee Energized" and "Super Green" are also misbranded within the meaning of section 403(i)(1) of the Act because they do not bear appropriate statements of identity. The statement of identity must be in terms of a common or usual name, such as "juice", or in the absence of a common or usual name, an appropriately descriptive term.

The products "Super Green" and "Bee Energized" are further misbranded within the meaning of 403(r)(1)(A) of the Act because they bear unauthorized nutrient claims. The claim "...Barley Grass is an excellent source of vitamins, chlorophyll, minerals and fiber" can not be used on the product "Super Green". The term "excellent source" has been defined by regulation as a synonym for "high", which has been defined as containing 20% or more of the Daily Reference Value (DRV) or Recommended Daily Intake (RDI) per reference amount customarily consumed. "Super Green" only contains 15% of Vitamin B6, 4% of Calcium and 12% fiber; which does not meet the requirements for the all-encompassing claim "excellent source of vitamins, minerals...and fiber." In addition, chlorophyll is represented as a nutrient in the context of its inclusion in the list of nutrients (vitamins, minerals and fiber). However, an RDI or DRV for chlorophyll has not been established; therefore "excellent source of...chlorophyll..." is not authorized and may not appear on the label of this product.

The claim "Bee Pollen is loaded with Amino Acids, enzymes, vitamins and minerals..." can not be made on the product "Bee Energized". The term "loaded with" is an implied nutrient claim for "high", which has been defined as containing 20% or more of the Daily Reference Value (DRV) or Recommended Daily Intake (RDI) per reference amount customarily consumed. A RDI or DRV for amino acids and enzymes has not been established, therefore "...loaded with Amino Acids, enzymes..." is not authorized for use and may not appear on the label of this product. In addition, some of the vitamins and minerals in this product do not meet the level required for use of the claim "loaded with." For example, the product only contains 2% of Vitamin A and 10% of iron. Therefore, the all-encompassing claim "...loaded with ...vitamins and minerals..." can not be used on the label of this product.

This letter is not intended to be an all-inclusive review of your firm's products, product labeling and promotional materials. It is your responsibility to assure that all products marketed by your firm are in compliance with the Act and regulations.

We request that you take prompt action to correct these violations. Failure to make prompt corrections may result in enforcement action being initiated by the Food and Drug Administration. This could include seizure of illegal products and injunctions against the manufacturer and/or distributor of the illegal products.

In addition, we offer the following comment regarding the labeling of your products "Apple Kiwi Papaya", "Orange Carrot Papaya", "Bee Energized" and "Super Green". Because these products are foods as defined in section 201(f) of the Act, and not dietary supplements, they can not display the Dietary Supplement Disclaimer statement.

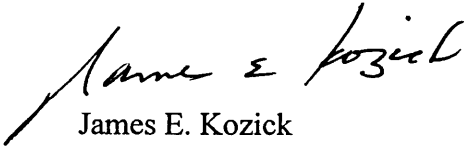
Please notify this office in writing within fifteen (15) working days of receipt of this letter describing the specific steps that you have taken to correct the violations and to prevent their

recurrence. If corrective action cannot be completed within the fifteen (15) working days, state the reasons for the delay and the time within which corrections will be completed.

Your written response should be directed to the attention of:

Thomas L. Sawyer  
Director, Compliance Branch  
Food and Drug Administration  
19900 MacArthur Blvd., Suite 300  
Irvine, CA 92612-2445

Sincerely,

A handwritten signature in black ink, appearing to read "James E. Kozick", is written over the typed name and title.

James E. Kozick  
Acting District Director